REMARKS/ARGUMENTS

Upon entry of the present amendment, claims 31-40, 43-44, 47, 49-50 are pending; claims 41-42, 45-46 and 48 have been cancelled without disclaimer or prejudice to renewal; and claims 31, 43 and 47 have been amended. Support for the amended claims can be found in the specification and claims as originally files and, thus, no new matter is introduced. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 31-50 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner has rejected claims 31 and 43, stating that it is unclear how hydrophilic compounds can be present in the lipid phase. Amended claims 31 and 43 no longer, explicitly or otherwise, recite "mucoadhesive compounds." This amendment was made, without prejudice, in the interest of furthering prosecution.

Amendments to the lipid compositions in claims 31 and 43 address the Examiner's concerns with regards to the same. Support for these amendments can be found in the examples on page 16 of the application as filed. Applicants believe that these amendments (to the independent claims 31 and 43) overcome the Examiner's concerns. Withdrawal of this rejection is requested.

Rejections Under 35 U.S.C. § 103

As set forth in M.P.E.P. § 2143, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's

disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Therefore, in order to establish a *prima facie* case, all three criteria must be met.

Rejection Under 35 U.S.C. § 103(a) Over Guo

Claims 31-50 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Guo (U.S. Patent No. 4,804,539).

As set forth above, both independent amended claims 31 and 43, as amended, recite the use of diclofenac, or its pharmaceutically acceptable salt. Both of the independent claims also recite use of liposomes for ocular applications. As pointed out by the Examiner, Guo fails to teach the specifically claimed anti-inflammatory agents and the eye conditions that result in the inflammatory conditions (see, page 4 of the Office Action).

The Examiner assumes that the guidance provided by Guo is sufficient for one of ordinary skill in the art to encapsulate specific drugs for various disease states and expect to have a reasonable expectation of success. Applicants respectfully disagree as not all drugs can be optimally encapsulated and delivered in a similar fashion. Moreover, specific areas of the body and specific disease states also require specific formulations, preparation of which encompass an inventive step.

In the absence of such teachings or suggestions (anti-inflammatory agents and the eye conditions that result in the inflammatory conditions) in Guo, the presently claimed methods are nonobvious and, thus, patentable over Guo. Accordingly, in view of the current amendments, Applicants urge the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 103(a) Over Guo in view of Touitou

Claims 41-42 and 46-48 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Guo (U.S. Patent No. 4,804,539) cited above, further in view of Touitou (U.S. Patent No. 5,716,638).

As set forth above, both independent claims 31 and 43, as amended, recite the use of diclofenac or its pharmaceutically acceptable salt. Both of the independent claims also recite the use of liposomes for ocular applications. As pointed out by the Examiner, Guo fails to teach

or suggest the specifically claimed anti-inflammatory agents and the eye conditions that result in the inflammatory conditions.

The formulations of Touitou, cited by the Examiner, contain high amounts of ethanol (or isopropanol). High amount of ethanol was indicated to be a preferred feature for delivery of the drug through skin (see, column 12, line 49-54 of Touitou). Applicants note that high levels of ethanol are not preferred for ocular delivery. Clearly, those of ordinary skill in the art would know and appreciate that ethanol is an eye irritant and, also, that liposomes prepared with high amounts of ethanol are unstable. Thus, Applicants submit that the teachings of Touitou in combination with the teachings of Guo do not make the currently claimed methods obvious. Accordingly, Applicants urge the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 103(a) Over Guo in view of Malerhofer

Claims 41-42 and 46-48 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Guo (U.S. Patent No. 4,804,539) cited above, further in view of Malerhofer (U.S. Patent No. 5,853,753) or vice versa.

As set forth above, both independent claims 31 and 43, as amended, recite the use of diclofenac, or its pharmaceutically acceptable salt. Both of the independent claims also recite the use of liposomes for ocular applications. As pointed out by the Examiner, Guo fails to teach the specifically claimed anti-inflammatory agents and the eye conditions that result in the inflammatory conditions. Again, as pointed out by the Examiner, Malerhofer does not teach the encapsulation of the anti-inflammatory drug diclofenac.

Absent such teachings or suggestions in Guo and Malerhofer, the presently claimed methods are non-obvious and, thus, patentable over the combination of Guo and Malerhofer. Accordingly, Applicants urge the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 103(a) Over Schaeffer in view of Malerhofer

Claims 31-50 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Schaeffer (*Invest. Ophthalmol. Vis. Sci.,* 1982) by itself or further in view of Malerhofer (U.S. Patent No. 5,853,753).

As set forth above, both independent claims 31 and 43, as amended, recite the use of diclofenac or its pharmaceutically acceptable salt. Both of the independent claims also recite use of liposomes for ocular applications. As pointed out by the Examiner, Schaeffer and Malerhofer do not teach or suggest the encapsulation of the anti-inflammatory drug diclofenac.

Absent such teachings or suggestions in Schaeffer and Malerhofer directed to the presently claimed lipid formulations and liposomes, the presently claimed methods are non-obvious and, thus, patentable over the combination of Schaeffer and Malerhofer. Accordingly, Applicants urge the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 103(a) Over Schaeffer in view of Malerhofer and Touitou

Claims 41-42 and 46-48 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Schaeffer (*Invest. Ophthalmol. Vis. Sci.,* 1982) by itself or further in view of Malerhofer (U.S. Patent No. 5,853,753) as set forth above, further in view of Touitou (U.S. Patent No. 5,716,638) cited above.

As set forth above, both independent claims 31 and 43, as amended, recite the use of diclofenac, or its pharmaceutically acceptable salt. Both of the independent claims also recite ocular applications. As pointed out by the Examiner, Schaeffer and Malerhofer do not teach or suggest the encapsulation of the anti-inflammatory drug diclofenac. Touitou does not cure the deficiencies of Schaeffer and Malerhofer. Touitou may disclose diclofenac, but the teachings of liposome formulations with ethanol make them unsuitable for ocular applications. Again, the cited references, either alone or together, amount to a teaching away since no more than an invitation to experiment is inferred.

Absent such teachings or suggestions in Schaeffer, Malerhofer and Touitou directed to the presently claimed lipid formulations and diclofenac, the presently claimed

methods are nonobvious and, thus, patentable over Schaeffer, Malerhofer and Touitou. Accordingly, Applicants urge the Examiner to withdraw this rejection.

In view of the foregoing (and additionally in view of the fact that the formulation of the present invention performs significantly and surprisingly much better that the currently marketed Voltraren Opthalmic® solution (see, a comparison is displayed in Table 1 on page 16 of the application as filed)), Applicants respectfully request that the Examiner withdraw all of the § 103 obviousness rejections.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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